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Hungary

Biotechnology

Annual Report

2007

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Report Highlights:
On November 27, 2006 the Hungarian Parliament approved the country's "coexistence regulation" (Amendment of the Act on Gene Technology Activities). With the new regulation Hungary imposed a "de facto" ban on biotech production due to neighbor consent requirements and excessive isolation distances. However, biotech opponents and advocates alike stress the country's need for biotechnology research. On February 20th, 2007 the EU environmental ministers voted down the European Commission's proposal for Hungary to repeal its prohibition on the use and sale of biotech corn "MON 810". The Hungarian Environmental Minister stressed that the decision was not against the production of genetically modified plants. However, he emphasized that Hungary wants to maintain safeguard measures until solid studies on the environmental effects are available. Hungary's biotechnology policy for feed corn production, corn seed production, and soybean product (soybean meal) imports negatively impacts U.S. exports to Hungary. Field corn and seed corn production (about one fifth of the EU's corn crop) is dominated by American varieties.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Budapest [HU1]
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Executive Summary

The GOH introduced the first Act on Biotechnology in 1998. Since then the Act has been amended several times. Last time, in November 2006, it was amended by adding the "Coexistence Regulation". Hungary's biotechnology legislation reflects preconceptions that the country's current "GM-free" status is a marketing boon. Most of efforts, however, blocking the new technology are coming from environmentalist groups and the Ministry of Environment. The GOH referenced the EU safeguard clause before imposing the ban on biotechnology varieties in 2005. The Council of Environmental Ministers have voted down the proposal of the European Commission to lift the ban two times, last on February 20, 2007.

Biotechnology Trade and Production--Status of Product Approvals

No biotechnology crop varieties are produced in Hungary. Three varieties have gone through field trials and are awaiting registration, including:

Field trials finished in 2003:

MEB 470 BT (DK 440 BTY) MON 810 code number corn borer resistant (MONSANTO)

NX 3035 (Alpha BT) Bt11 code number corn borer resistant (Syngenta)

X 0987ZT MON 810 code number corn borer resistant (Pioneer Hi-Bred Rt.)

The Ministry of Agriculture and Rural Development (MARD) refused to approve the registration of the above varieties because of the moratorium on MON 810 varieties, and the lack coexistence regulation beforel November 2006.

Additional corn varieties subject to field trials previously were:

MEB 471 RR (DK 440 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

MEB 391 RR (DK 391 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

X1019VT BT code number corn borer resistant (PIONEER Hi-Bred Rt.)

Above varieties either failed to meet the requirements of the variety registration or were withdrawn by their owner. Currently, no biotechnology corn varieties are undergoing registration trials in Hungary.

On January 20, 2005, the Government of Hungary (GOH) imposed a moratorium on corn varieties containing the MON 810 event.

The four main reasons for the moratorium were the following:

1). The negative results of an environment effect study. The research carried out in Hungary under the direction of the Plant Protection Institute of the Hungarian Academy of Sciences focused on genetically modified maize DK 440 BTY containing the genetic construction YieldGard™ MON 810. Laboratory and small-scale parcel field experiments showed that the long-term presence of the plant might have adverse effects on the ecosystem. (*Darvas et al. (2003)* EFFECT OF POLLEN OF DK-440-BTY (YIELDGARD) BT MAIZE ON THE LARVAE OF *INACHIS IO* L. (NYMPHALIDAE) Hungarian Academy of Sciences, Plant Protection Institute, Ecotoxicology Department, Budapest)

2). The need to repeat the late 1990s EU trials using contemporary methodology for this event.

3). The specific ecological conditions of the " Pannonian biogeographic region" (a region containing parts of Hungary, Austria, and Slovenia) questions the validity of risk assessment based on the ecosystems of the older Member States, owing to its different environmental features.

4). Hungary had no coexistence regulation when the moratorium was launched.

Hungary is an active participant in the development of biotechnology crops at the basic science level, as well as in the research of the environmental, feeding, etc. effects of these crops in cooperation with other countries.

Hungary does not import biotechnology crops, but imports soybean meal, peanut butter, sauces and other products containing biotech raw materials.

Biotechnology Policy--Regulatory Framework

In the case of green (agricultural) biotechnology, the Ministry of Agriculture and Rural Development(MOA) takes the lead concerning the cultivation, importation, and processing into food/feed. The Hungarian Food Safety Authority (FSA) under the Ministry of Health (MOH) is the top umbrella organization, but most of the administrative responsibilities and the institutional background belong to the MOA. The Ministry of Environment and Water Management (MOE) handles certain biotechnology regulation portfolios and also participates in the work of the Biotechnology Committee (BC). MOH is responsible for the red biotechnology (medicinal use), and the Ministry of Economy and Transport (MET) handles foreign trade and strategic investment affairs. Both the MOH and the MET are advocates of biotechnology as the key to further economic development but firmly differentiate between red (thought of positively) and green (thought questionably) biotechnology.

The Biotechnology Committee (BC) has a key role in evaluating the applications (new varieties, genes, etc.) although the approval is formally made by the MOA. The committee is composed as follows: the Hungarian Academy of Science (MTA) may delegate five members, the relevant Ministries (MOA, MET, MOH, MOE) and the Ministry of Education delegate one each, and NGOs may nominate seven delegates (including one by the pro-biotech Zoltan Barabas Biotechnology Association) to the 17 member BC. Civil Servants (government employees) are not members of the BC. Ministries nominate scientists or experts from 'think tanks' belonging to their Department. The "independent" BC sets its own rules, supposing that the question is not regulated in the Act No. XXVII. of 1998 On Biotechnology (amended by Acts No. LXVII. of 2002, and No. CVII. of 2006) or elsewhere (e.g. 111/2003. (XI.5.) Order of Ministers of MARD, MET, MH, and MEW on Genetic Modification and Like Processes, and their Inspection Authorities).

Administrative and service charges of the Committee and other authorities inspecting biotechnology experiments are set in the 138/2004. (IX.23) Order of the Minister of MARD on the administrative and Service Fees for the Approval of Gene-technology Activities.

Regulatory decisions may be influenced by different political factors, including:

- EU market orientation of Hungary's corn and corn seed production. Traditionally strong cooperation with Austria and Germany, main opponents of GMOs.

- The Hungarian consumer is pragmatic, but domestic and international green organizations are increasingly active in Hungary.

Politicians, government officers, journalists and sometimes scientists are shy to express their opinions about biotechnology or even participate in topical seminars.

- Most of reasons blocking the new technology are coming from environmentalist groups and the Ministry of Environment and Water Management (MEW). MEW has turned down applications of biotechnology industry companies for environmental effect experiments, although the applications had the approval of the Biotechnology Committee.

Biotechnology Research

Besides testing biotechnology crop varieties, Hungarian biotechnology laboratories are dealing with the analysis of different GMO materials. Use of these biotechnology materials (for variety field test or any other feeding, environmental effect, etc. trials) must also be approved by the BC. According to a BC decision, stacked events are taken for new events, considering possible cross effects. Lists of biotechnology materials and programs are available at the website of the Godollo Agricultural Biotechnology Center (www.abc.hu) and the website of the EU Commission, Directorate General, Joint Research Centre (http://biotech.jrc.it) quoted in ANNEX I.

Researchers of the "Pannonian Region" countries established the "Pannonian Region Agricultural Biotechnology Association" in June 2006. The partnership of respected scientists and plant breeding and seed business entities from Austria, Czech Republic, Hungary, Slovakia, Slovenia, Romania, Croatia, Bosnia-Hercegovina, Serbia, and Ukraine plan to facilitate regional collaboration, information exchange, and to assist country based biotechnology efforts.

Coexistence Regulation

The MOA finished the drafting and first panel discussions of the Hungarian Coexistence Regulation in June 2005. The draft was sent for Commission approval on October 15, 2005. The drafting period (first half of 2005) included vivid discussions at different government and NGO forums. Representatives of the biotechnology industry and the Biotechnology Association participated in the work of the Coexistence Working Committee.

The Commission sent back its detailed opinion on the draft to the MARD in March 2006. The Commission's opinion proposed corrections in the draft Coexistence Regulation.

- In some instances (i.e. the ban of EU listed varieties and the request for further environmental risk assessments), the GOH wants to regulate issues that are harmonized at the EU level.

- In the case of producer liability, the Commission stressed that measures, including liability rules must be proportionate with the objectives and potential risks.

Despite of the dissatisfaction of the science community, and the Biotechnology Association, the main lobbying organization of the biotechnology research and industry in Hungary, the GOH approved the Coexistence Regulation with minimum alterations on November 27, 2006 (See our report HU6015). The Coexistence Regulation (Act CVII. of 2006) is the amendment of the Act No. XXVII. Of 1998 On Biotechnology. The most debated provisions of the final Coexistence Regulation remained the prior written consent requirements of all landowners

and land users of the neighboring parcels and the big isolation distances required between biotech and conventional or organic crop fields.

Other Member States of the EU require only notification or coordination with neighbors. The written permit means a "de facto" ban on biotech crop production because parcels owned by individual holders are small in Hungary and due to the system of the early 1990's Cooperative Land Re-privatization program, larger fields often belong to joint (undivided) property of many proprietors. The majority of agricultural land is cultivated by medium or large size farms under long time contracts. These farmers need to make an agreement with not only the numerous owners of neighboring fields, but with the users of these fields as well, supposing the two are not the same. Some large scale agricultural corporations which lease state owned land may be in the position to try the new technology. However, only if the Government of Hungary, as a proprietor, approves it.

The isolation distance set by the Coexistence Regulation for corn is 400 meter, more than double that of the distance used in hybrid seed propagation worldwide and much larger than the required isolation in Member States already producing biotech crops. According to the calculation of a seed firm, in the case of a 400-meter isolation for a 100 hectare rectangular field, only 4 hectares of biotech corn could be planted. Or if an average of a 30-hectare field was planted with biotech corn, then the 152 hectares surrounding it should be planted with other crops than corn.

Labeling rules

Act No LXXXII of 2003 on Food is a general, "umbrella" piece of legislation. The Act does not contain the domestic versions of EU (European Council or Commission) directives, so it does not need to be revised whenever any EU directive is changed. The domestic directives are contained in the **Hungarian Food Codex (HFC)** or other separate legal rules (such as legislation for Wine, for Mineral Water, and for Meat and Meat Products). General prescriptions of the Act must be applied together with HFC directives and other corresponding regulations.

All kinds of food, including food imported for commercial sale, fall under the ruling of the Act. (Products from other EU member countries are considered as domestic products (§7. (2)) See the Act on Food in English at http://www.fvm.hu/files/elelmiszeripar/elszi_5_en.pdf

Other corresponding regulations include:

19/2004. (Feb 26.) Order of the Min of Agr-Min of Health-Min of Economy On labeling of Foodstuffs

138/2004 (Sep 23.) Order of the Min of Agriculture On the administrative and Service Fees for the Approval of Gene-technology Activities

e.g. -Fees for the approval of commercial sales of GMOs and products thereof

-Fees for the approval of the export-import trade of above products

142/2004. (Sep 30.) Order of Min of Agr-Min of Economy On Some Rules of Gene-technology Activities in Agriculture and Industry

e.g. Labeling of products containing GMOs (above the threshold level).

Hungary is not an importer of biotech products, excluding animal feed.

Plant propagation materials (seeds) go through systematic sampling and laboratory analyses. However, for feed and food, where the exporter must declare the quality of the product, only random sampling takes place.
The accredited laboratory for biotechnology testing is the Biomi Kft., a joint venture between the Agricultural Biotechnology Center at Godollo and the Dr. E. Wessling Chemical Laboratory Kft. (www.biomi.hu)

Cartagena Biosafety Framework

Hungary has ratified the Biosafety Protocol. The legislation is the CIX./2004. Act on the Promulgation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The implementation rules of the Act have not yet been prepared.

Capacity Building and Outreach

Since the previous Biotechnology Annual Report post has been involved in the following biotechnology events:

August 18, 2006	Dr. Robert Beechy, Danforth Research Center, Saint Louis, meeting with Hungarian Agribusiness representatives at the Embassy
October 12	Dr. T.G. Alister Clemence, Regulatory Affairs Lead, Europe-Africa, Monsanto, Brussels and Ms. Annick Pleysier, Jr. Reg Affairs Manager met with Embassy team
November 16	Plant Biotechnology in the Great Pannonian Region. International conference at the Hungarian Academy of Science
November 21	Crops Developed by Gene Technology – Farmers' Forum
November 22	Open Day of the Hungarian Parliament on Biotechnology and Coexistence at the Hungarian Parliament
January 16, 2007	Discuss plans for a "Pannonian" Region Agricultural Biotechnology Association meeting in April with Messrs. Bedo and Czepo over a lunch in Budapest
March 1	"Biotechnology Dinner" at the AMB Residence
March 8	Presentation of Mr. Clive James, Director, ISAAA on the Results of Agricultural Biotechnology in the Last Decade, at the Hungarian Academy of Science. Lunch with Mr. James, Mr. Denes Dudits. Mr. Mihaly Czepo, and Zsolt Jekkel.
May 22	Visit of a senior executives delegation of Monsanto, headed by CEO Hugh Grant. Meeting at the Embassy.

The introduction of biotechnology varieties in the neighboring countries may facilitate the acceptance of the technology in Hungary. Pro-biotech institutions and

persons of the countries neighboring Hungary and with similar ecological conditions, have established the "Pannonian" Plant Biotechnology Association to coordinate their activities in 2006. The Greater Pannonian region includes Romania, Hungary, Serbia & Monte Negro, Czech Republic, Croatia, Slovakia, Austria, Slovenia, and covers the total area of 24,951 million hectares of arable land. Post maintains continuous connections with the Association and facilitates its conferences in the region.

Biotechnology related reports issued since the last Annual Report

HU6013 Moratorium and Coexistence Regulation Update

HU7004 Hungary's Biotech Corn Ban Remain in Place

ANNEX

I. Current biotechnology research (Deliberate releases) – Hungary, 2007

Notification number	State	Pub. Date	Name of the Institutes or Companies	Project title
B/HU/06/11/6	Hungary	22/12/2006	Monsanto Kereskedelmi Kft	Three year field trials programme (2007-2009) for the deliberate release of MON 88017 maize protected against certain coleopteran insect pests (Diabrotica spp) and tolerant to glyphosate
B/HU/06/11/7	Hungary	22/12/2006	Monsanto Kereskedelmi Kft	Three year field trials programme (2007-2009) for the deliberate release of MON 88017 maize protected against certain coleopteran insect pests (Diabrotica spp) and tolerant to glyphosate
B/HU/06/11/8	Hungary	5/1/2007	Agricultural Research Institute of the Hungarian Academy of Sciences	Field trials programme for the deliberate release of MON 88017 maize protected against certain coleopteran insect pests (Diabrotica spp) and tolerant to glyphosate
B/HU/06/12/1	Hungary	29/01/2007	Syngenta Seeds Kft. Hungary	Field trials with genetically modified glyphosate tolerant maize event GA21 to be carried out between 2007 and 2010.

B/HU/07/01	Hungary	20/02/2007	Agricultural Research Institute of the Hungarian Academy of Sciences	In vivo transformation of Martonvásár maize lines using the genetically modified maize containing Roundup Ready ® genes (NK603 glyphosate tolerance)
B/HU/07/02	Hungary	20/02/2007	St. Stephen University	Field trial program of genetically modified maize varietie tolerant to two herbicides (DP-098140-6)
B/HU/07/03	Hungary	20/02/2007	St. Stephen University	Application for the deliberate release of genetically modified DP-Ø9814Ø-6xDAS-Ø15Ø7-1 maize
B/HU/07/04	Hungary	20/02/2007	St. Stephen University	Application for the deliberate release of genetically modified DP-Ø9814Ø-6xDAS-Ø15Ø7-1xDAS-59122-7 maize
B/HU/07/05	Hungary	20/02/2007	St. Stephen University	Field trials program with genetically modified maize variety resistant to certain Coleopteran insects.